REMARKS

Entry of the foregoing and further and favorable reconsideration of the subject application, in light of the following remarks, is respectfully requested. Claims 1, 4-16, 22-25, 31-32, and 37-50 are currently pending in this application. Claims 7-16, 22-25, 31, 32, 37-42, 44, and 45 have been withdrawn from consideration. Claims 2, 3, 17-21, 26-30, and 33-36 were previously cancelled without prejudice or disclaimer of the cancelled subject matter. Applicant reserves the right to pursue any cancelled subject matter in one or more continuing or divisional applications. Claims 46-50 are newly added. Claims 1, 4-6, 43, and 46-50 are under examination.

By the present amendment, Claims 1, 4-6 and 43 have been amended to make clear that the antibody binds to an ubiquitination-regulating domain (or a functional fragment thereof) within SEQ ID NO:1. Support for this amendment to the claims may be found, at the very least, on page 2, line 20, to page 3, line 4, of the specification as filed.

Furthermore, withdrawn claims 15, 16 and 32 have been amended to re-insert the step identifiers (*i.e.* (a), (b) and (c)) which were inadvertently left out in the Amendment filed October 31, 2005.

Support for new claims 46-50 is found, for example, page 2, line 20, to page 3, line 9, of the specification as filed; in original claims 1, 4-6, and 43; and, elsewhere throughout the specification.

It is believed no new matter enters by the present amendment and entry is respectfully requested.

Interview Summary

Applicants wish to thank Examiners Fetterolf and Siew for holding a personal interview on August 29, 2006 with the undersigned. During the interview, the teachings of the Li and Brie documents were discussed. It was agreed that Applicants would provide amendments and arguments to overcome the pending rejections of claims 1, 4-6

and 43. The amendments to the claims, and arguments below, are believed to overcome the rejections. New claims 46-50 are believed to be free of the rejections.

Rejections

A. Rejection of Claims 1, 4-6, and 43 Under 35 U.S.C. § 112, First Paragraph

Claims 1, 4-6, and 43 remain rejected under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. The rejection is respectfully traversed. For at least all of the reasons set forth below, withdrawal of this rejection is believed to be in order.

By the present amendment, the claims have been amended to make clear that the ubiquitination-regulating domain, or fragment thereof, to which the antibody binds is within SEQ ID NO: 1. As noted previously, the written description requirement for a claimed genus may be satisfied by describing a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, such as functional characteristics coupled with a known or disclosed correlation between function and structure. *See* MPEP § 2163 IIA3(a)(ii) and *Reagents of University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). Not only does the specification provide reduction to practice of a representative number of species of fragments of the ubiquitination-regulating domain of SEQ ID NO:1 (see, for example, the fragments of SEQ ID NO:1 listed on page 24, last paragraph, of the specification), it also discloses functional characteristics shared by all of the species and a correlation between function and structure (see, for example, page 12, lines 3-4; page 26; and Figure 3(a) of the specification as filed).

Therefore, Applicants have not only identified a representative number of species of fragments of the ubiquitination-regulating domain of SEQ ID NO: 1, they have also identified functional characteristics shared by all of the species as well as a correlation between the function and structure.

Furthermore, as noted by the Federal Circuit in Noelle v. Lederman, 355 F.3d 1343, 1349 (Fed. Cir. 2004) "...as long as an applicant has disclosed a "fully characterized antigen," either by its structure, formula, chemical name, or physical

properties...the applicant can then claim an antibody by its binding affinity to that described antigen." In the present case, Applicants have fully characterized the antigen by its structure, *i.e.* the ubiquitination-regulating domain within SEQ ID NO: 1, or a functional fragment thereof. Therefore, the specification clearly provides written description support for the antibodies that bind to the fully characterized antigen.

Finally, as noted above, by the present amendment, the claims have been amended to make clear that the ubiquitination-regulating domain, or fragment thereof, to which the antibody binds is within SEQ ID NO:1. It is thus clear that the written description requirement has been met. For the foregoing reasons, new claims 46-50 are free of the rejection.

In light of these remarks, reconsideration and withdrawal of this rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

B. Rejection of Claims 1, 4-6, and 43 Under 35 U.S.C. §102(b)

Claims 1, 4-6, and 43 remain rejected under 35 U.S.C. §102(b), as being allegedly anticipated by Li *et al.* (US 5,891,668). Claims 1, 4-6, and 43 also remain rejected under 35 U.S.C. §102(b), as allegedly being anticipated by Brie *et al.* (US 5,892,016). These rejections are respectfully traversed. For at least all of the reasons set forth below, withdrawal of these rejection is believed to be in order.

The claimed invention is directed to an isolated antibody that binds to a polypeptide comprising the amino acid sequence recited in SEQ ID NO:1, wherein said antibody binds specifically to a ubiquitination-regulating domain, or functional fragment thereof, within SEQ ID NO:1.

According to the Examiner, Li *et al.* teaches antibodies produced to normal and mutated forms of TSG101. Furthermore, the Examiner asserts that Brie *et al.* teaches antibodies raised against an amino acid sequence that allegedly has 100% sequence identity to the amino acid sequence of SEQ ID NO: 1. The Examiner admits that neither of these references disclose an antibody that binds to a polypeptide comprising a ubiquitination-regulating domain, but states that the antibodies disclosed in Li *et al.* and Brie *et al.* would inherently bind to such a polypeptide. Applicants respectfully disagree.

It is incumbent upon the Examiner to show that the allegedly inherent characteristic (in this case, the ability of an antibody to bind to a ubiquitination-regulating domain, or functional fragment thereof, within SEQ ID NO:1) necessarily flows from the teachings of the art. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (BPAI 1990). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.'" *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999). *See also* MPEP § 2112(IV). Furthermore, "inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *Continental Can Company USA v. Monsanto Company*, 948 F.2d 1264, 1269 (Fed. Cir. 1991). The purpose of "inherent anticipation" is to accommodate "situations where the common knowledge of technologists is not recorded in the reference; that is, where technological facts are known to those in the field of the invention, albeit not known to judges." *Id.* To interpret the theory of "inherent anticipation" any broader would contravene long-established precedent. *See Tilghman v. Proctor*, 102 U.S. 707 (1880) where the Supreme Court found that it would be "absurd" to hold a patent to be anticipated because prior to the patents finding the invention was "accidentally and unwittingly produced whilst the operators were in pursuit of other and different results, without exciting attention and without its even being known what was done or how it had been done."

In the present case, the Office has not met the burden of showing the allegedly inherent characteristic (in this case, the ability of an antibody to bind to a ubiquitination-regulating domain, or functional fragment thereof, within SEQ ID NO:1) necessarily flows from the teachings of the art. One of skill in the art, reading the disclosures of either Li *et al.* or Brie *et al.*, would not have recognized or appreciated whether the antibodies disclosed therein would bind to a ubiquitination-regulating domain, or functional fragment thereof, within SEQ ID NO:1. This is especially true because neither of Li or Brie, recognized or appreciated that the full length protein had a ubiquitination-regulating domain.

Therefore, neither of the Li or Brie documents "inherently anticipates" because the technological fact of a "ubiquitination-regulating domain" present in the full-length protein was not disclosed or recognized by either of Li or Brie, both of whom clearly qualify as "technologists in the field." Further, the fact that not just one, but two "technologists" failed to recognize or appreciate the presence of a "ubiquitination-regulating domain" in the full length protein is additional evidence supporting the novelty of the invention as claimed.

Whether an antibody that falls within the scope of the claimed antibody was "accidentally" produced by either Li *et al.* or Brie *et al.* is irrelevant, as one of skill in the art would not have recognized from the disclosures whether such an antibody was produced or not – such a recognition is required to establish "inherent anticipation." Therefore, in following the Supreme Court's long held precedent in *Tilghman v. Proctor*, it would be "absurd" to hold the claimed invention to be anticipated by either of these references.

If the Office maintains these rejections, the Office is respectfully requested to provide citations to the Li and Brie documents, showing where each of Li and Brie recognized or appreciated the presence of the "ubiquitination-regulating domain" in the full length polypeptide. Contrary to the opinion of the Office, similarity of amino acid sequence does not provide one of skill with the recognition required to establish "inherent anticipation." And, antibodies specifically binding to the ubiquitination-regulating domain would not be expected to bind elsewhere to the polypeptide.

For reasons discussed above, new claims 46-50 are patentable over the Brie and Li documents as well. Because the Office has failed to present a legally sufficient case of anticipation, the rejections under 35 U.S.C. § 102(b) are legally improper.

Reconsideration and withdrawal of the rejections under 35 U.S.C. § 102(b) is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, Applicants respectfully request a Notice of Allowance. If the Examiner believes a telephone conference would advance the prosecution of this application, the Examiner is invited to telephone the undersigned at the below-listed telephone number.

Respectfully submitted,

MERCHANT & GOULD P.C.

September 28, 2006
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